K120187

510(k) Summary

APR - 6 2012

Submitter's Name:	IGT, LLC dba Eigen
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Contact Name:	William Mandel
Date Summary was Prepared:	21 Oct 2011
Trade or Proprietary Name:	Multi-Modality Image Fusion
Common or Usual Name:	Multi-Modality Image Fusion
Classification Name:	System, Image Processing, Radiological, LLZ Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
Syntegra	K041182
UniSyn	K081987
Aegis Navigation	K093672
Abaris	K053610

Intended Use

Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

Description of the Device and Summary of the Technological Characteristics:

Multi-Modality Image Fusion (MMIF) is software, which comprises of two software components, which is referred to as offline and online. The offline component pertains to the preparation of gland and suspected lesion boundaries on a DICOM image file days or hours prior to the biopsy procedure. The online component fuses the DICOM image files, which were, prepared on the offline component, with a snap shot incoming TRUS image. Each of the two software components can work together or independently.

Offline Software

The offline software can delineate suspected areas of interest using visualization and save this data in a standard format, e.g. as a surface mesh in VTK or STL format. Furthermore, the

offline software can optionally delineate the gland boundary from a DICOM image, or other volumes where the boundary can be easily observed. This addition data is also saved in a standard format, e.g. surface mesh in VTK or STL or as a binary volume. This software would be typically executed by Radiologists.

Online Software

The online unit software is designed to fuse two images by entering a fusion mode and load the DICOM image and the boundary data provided by the offline unit. The online unit performs rigid alignment, either selecting globally align that orients the two DICOM volumes based on the known relative orientation difference between the two or specify landmarks to register images rigidly. The online unit then elastically warps the image to register on the incoming image from the offline unit.

The registered image volume is displayed on the incoming offline image frame of reference. Also overlaid on the incoming offline and registered image volumes annotating the suspected lesion boundaries. The two volumes are displayed side-by-side in a locked view. Rotation, slicing, panning, or zooming one of the volumes has the same effect on the other enabling visualization of similar features in both volumes simultaneously.

Plan targets on the volumes by selecting suitable locations within the suspected areas of interest boundary. When sufficient targets have been added, exiting fusion mode imports all targets planned in the offline frame of reference back to the original reconstructed ultrasound volume. This is done based on the deformation field that was estimated from registration (rigid followed by elastic registration).

Substantial Equivalence:

Manufacturer	**Eigen**	**ADAC Laboratories**	**Convergent Imaging Solutions**	**Sentinelle Medical Inc.**	**Traxtal Technologies Inc.**
Product Name	**Multi-Modality Image Fusion**	**Syntegra**	**UniSyn**	**Aegis Navigation**	**Abaris**
510(k) number	pending	K041182	K081987	K093672	K053610
Intended Use	Multi-Modality Image Fusion is a software application used by	Syntegra is a software application for multi-modality	UniSyn is a software application for image	This device provides two and three-dimensional image review,	ABARIS is a stereotaxic accessory for Computed

	physicians in the clinic or hospital for 2-D and 3-D visualization, multi-modality image registration, and fusion of medical images. Additional software features include database management, communication, surface rendering, segmentation, ROI delineation, measurements, and reporting.	image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals	registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image	manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices. This device is intended to assist skilled medical professionals in clinical screening and	Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. it displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device. The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for

				interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.	visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.
Where Used	Office settings in clinic or hospital	Office settings in clinic or hospital	Office settings in clinic or hospital	Not specified	clinical interventions
Software Device	Yes	Yes	Yes	Yes	Yes
Image Registration	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration	Yes
Image Fusion /Overlay Display	Fused overlay of images from multiple modalities	Fused overlay of images from multiple modalities	Fusion overlay of images from multiple modalities	overlay of images from multiple modalities	Yes
Opacity Control	Yes	Yes	Yes	Not Specified	Not Specified
3-D Rendering	Yes	Yes	Yes	Yes	Yes
Surface Rendering	Yes	Yes	Yes	Yes	Yes
Regions of interest	Yes	Yes	Yes	Yes	Yes
Configura	Yes	Yes	Yes	Yes	Yes

ble image layouts					
3D Contourin g	Yes	Not Specified	Yes	Yes	Yes
Export of 3D contours for planning	Yes	Not Specified	Yes	Not Specified	Yes
Image Storage and Communic ation	DICOM, JPEG	DICOM (check)	DICOM	DICOM	DICOM
Modalities	CT, MRI, Ultrasound	Positron Emission Tomography (PET) and X-ray Computed Tomography (CT).	CT, PET, SPECT and MR scanners	MRI, US, SPECT, CT, PET, Fluoroscopy, Endoscopy and others	Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems

The product's technical features are substantially equivalent to Syntegra (K041182), UniSyn (K081987), Aegis Navigation (K093672) and Abaris (K053610). The Multi-Modality Image Fusion is a software product that runs on PC-based workstations. Image data is input to the devices and used to generate 3-D views and perform image processing. Like the four predicate devices, the software has image measurement, multi-planar reformatting, segmentation and image registration abilities, fusion of images from different modalities, image storage and retrieval, as well as patient information management functions.

The Syntegra and UniSyn are software products that accept multiple image data types including magnetic resonance, and computed tomography. Aegis Navigation and Abaris are systems that accept multiple modalities that include magnetic resonance, computed tomography and ultrasound. The Multi-Modality Image Fusion has been designed for processing medical images in standard DICOM format. The system is composed of two modules: an offline and an online module for image fusion for planning a procedure.

Testing and Performance Data:

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were developed and were used to verify system performance.

The device has been designed and manufactured to conform to the following standards:

ACRINEMA PS3.1-3.18 Digital Imaging and Communications in Medicine (DICOM)

ISO 14971 Application of Risk Management to Medical Devices

ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

The following tests were performed:

MMIF Hardware verification Test Procedure

MMIF Online Verification Test Procedure

MMIF Offline Software Application Verification Test Procedure

MMIF Risk Mitigation Verification Test Procedure

Registration Accuracy for Clinical Data (bench test)

Phantom Volume Measurements (bench test)

Phantom Registration Accuracy (bench test)

All the above mentioned tests passed. Theses testing activities were conducted to establish the performance, safety, effectiveness, functionality usability, and reliability characteristics of the new device.

The purpose of the performance testing (bench testing) was to ensure the performance of the new MMIF software by verifying the accuracy of the specifications and simulating real customer data collected from the hospital setting.

The conducted verification tests have confirmed static and dynamic performance of the complete system consisting of both the online and off line software installed on specified hardware. Furthermore these tests establish compliance to the specification under conditions simulation real environment of use.

Conclusion:

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of the Multi-Modality Image Fusion with those of the two predicate devices demonstrate that the Multi-Modality Image Fusion is substantially

equivalent to existing products on the market today.

The verification and validation testing included bench performance tests, functionality tests, and system test. All tests were successfully completed.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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APR - 6 2012

Re: K120187
Trade/Device Name: Multi-Modality Image Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications System
Regulatory Class: II
Product Code: LLZ
Dated: March 1, 2012
Received: March 2 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known):

Device Name: Multi-Modality Image Fusion

Indications for Use: Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

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